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11/8/01

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November 8, 2001

Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

To Whom It May Concern:

I am a graduate student in Social Work at Southern Connecticut State University with a special interest in mental health. I am writing to request a critical reevaluation of the scheduling of 3,4-Methylenedioxymethamphetamine (MDMA). Before MDMA was placed into schedule I in 1985, it was used legally in the treatment of a variety of psychiatric conditions with anecdotal reports of efficacy and safety. Unfortunately, controlled studies were not performed and the MDMA treatment model remains neither proven nor disproven.

Of the possible clinical indications for MDMA, the treatment of Posttraumatic Stress Disorder (PTSD) appears especially promising. PTSD has an 8% lifetime prevalence and is often treatment resistant. Despite the improved understanding of the neurobiology of PTSD, the efficacy of current therapeutic options is woefully inadequate resulting in personal devastation and high costs to society.

A Spanish research group at the Psychiatric Hospital of Madrid is currently conducting a study using MDMA-assisted psychotherapy of PTSD in victims of sexual assault who did not benefit from conventional treatment. Preliminary findings are promising. However, studies like this must be replicated and extended to assess the efficacy of this treatment modality.

The major obstacle to clinical research in the United States is MDMA's classification as a schedule I drug. The decision to place MDMA into schedule I was an alarmist response to recreational use without appropriate regard for its potential as a therapeutic agent. Recreational use and clinical treatment models must be clearly distinguished as it is for opiates. There is no question that MDMA abuse is associated with significant health risks. However, these risks are significantly reduced when MDMA is administered in therapeutic doses under controlled conditions. Moreover, the MDMA treatment model uses the drug infrequently thereby reducing risks. (A comprehensive, 367-page literature review on MDMA research can be downloaded in PDF format at http://www.maps.org/research/mdma/protocol/litreview.html)

I think it is time to reconsider MDMA's scheduling and place it in schedule II in order to make it available to clinical researchers. In light of the recent and possibly future terrorist attacks and the possibility of war, it is our moral obligation to pursue all treatment options that have the potential to help innocent victims of trauma.

A response to my request before November 13, 2001 is much appreciated.

Sincerely,
Heike Karsch
Heike Karsch

OIP-0517 CP 1

Facsimile Transmission

Cover Sheet

To:	**FDA Dockets Management Branch**
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Number of Pages faxed: **2**

Note: Addended is a letter I submitted for consideration approximately 6 weeks ago. Of the items you require, the letter contains the action requested and a statement of grounds. It does not contain any information on the environmental or economic impact. There should be no environmental impact and the economic impact is unknown since it is contingent on future research results.

Certification: I submit this petition for consideration of a policy change and certify that the information contained is true to the best of my knowledge.

Heike Karsch

I would very much appreciate some kind of response to this request. I feel very strongly about this cause and hope that my petition will be given serious consideration. Thank you.